MD

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,821	09/30/2002	Hans-Jurgen Maier	5088	8018

26936 7590 06/30/2004

SHOEMAKER AND MATTARE, LTD
10 POST OFFICE ROAD - SUITE 110
SILVER SPRING, MD 20910

EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,821	MAIER ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 15-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 15-34 is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 24 is objected to because of the following informalities: In Claim 24 the term tartaric is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "mixtures thereof" in for the fruit acid present in the formulation of claim 18. There is insufficient antecedent basis for this limitation in the claim. Claim 18 is drawn to a composition comprising only a (single) fruit acid.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-22, 28, 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Demopoulos (EP 0444000).

Claim 15 is drawn to a solid formulation of glucosamine sulfate or a mixed salt thereof in an effervescent preparation. Dependent claims 16-22, 28 and 31are drawn to the composition of

claim 15 further comprising specific amounts of glucosamine sulfate, a fruit acid for storage stability, specific ratios of the glucosamine sulfate or mixed salt and fruit acid; wherein the fruit acid is hydroxylated and anhydrous and wherein the composition further comprises an antioxidant.

Demopoulos teaches a composition comprising glucosamine sulfate, ascorbic acid and calcium carbonate (see abstract, col. 2, line 40 through col.3, line 8, limitation of claim 15). The composition is can be formed into a capsule or tablet (solid formulation, col. 7, lines 48-50, limitation of claim 15). The formulation typically comprises 50mg to about 1500mg of glucosamine sulfate in a single dosage (col. 6, lines 32-38, limitations of claims 16-17). The composition is in a highly storage stable form (col. 2, lines 40-42, limitation of claim 18). The formulation can contain ascorbic acid (a hydroxylated fruit acid, meets limitation of claim 22) from 25 to about 100mg (col. 6, lines 43-49, this teaching in combination with the amount of glucosamine sulfate meets the limitations of claims 19-21). The ascorbic acid used in the formulation can be conventional dry powder (anhydrous, col. 4, lines 27-34, meets limitation of claim 28). Ascorbic acid is an antioxidant (limitation of claim 31).

Demopoulos teaches in Example 1 (col. 8) the preparation of a composition comprising glucosamine sulfate, calcium carbonate and ascorbic acid (fruit acid). The active agents are all dry solids. Since the formulation has a carbonate as the base in the presence of an acidic substance it is an effervescent preparation. This teaching is seen to meet the limitation of instant claim 32.

Claims 32-33 are product by process claims, the product being the formulation of claim15, which is a formulation comprising glucosamine sulfate or a mixed salt thereof in an

effervescent preparation. The composition of Demopoulos is seen to meet the limitations of claims 32-33. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koji et al (JP 1192385 and English Abstract) in combination with Demopoulos (EP 0444000), Schleck et al (US 5,843,923), Rovati (US 3,683,076) and The Merck Manual (12th Edition, 1996, page393-393).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 15 is drawn to a solid formulation of glucosamine sulfate or a mixed salt thereof in an effervescent preparation. Dependent claims 16-22, 28 and 31are drawn to the composition of claim 15 further comprising specific amounts of glucosamine sulfate, a fruit acid for storage stability, specific ratios of the glucosamine sulfate or mixed salt and fruit acid; wherein the fruit acid is hydroxylated and anhydrous and is an aliphatic carboxylic organic acid, wherein the mixed salt is glucosamine potassium chloride and wherein the composition further comprises an antioxidant.

Koji teaches a composition comprising glucosamine hydrochloride and an organic acid. The organic acid can be a 1-8 carbon mono, di or tricarboxylic acid or a hydroxyacid (english abstract). Koji's composition is stable even in the liquid form. The composition of Koji also comprises lemon juice (citric acid-an aliphatic hydroxylated carboxylic acid, see Japanese patent

JP 11-92385, bottom of page 3) and ascorbic acid (antioxidant). However, Koji does not teach a solid composition comprising glucosamine sulfate or the use of mixed salts of glucosamine or the use of an antioxidant in the composition.

Demopoulos teaches a composition comprising glucosamine sulfate, ascorbic acid and calcium carbonate (see abstract, col. 2, line 40 through col.3, line 8). The composition is can be formed into a capsule or tablet (solid formulation, col. 7, lines 48-50). The formulation typically comprises 50mg to about 1500mg of glucosamine sulfate in a single dosage (col. 6, lines 32-38). The composition is in a highly storage stable form (col. 2, lines 40-42). The formulation can contain ascorbic acid (a hydroxylated fruit acid) from 25 to about 100mg (col. 6, lines 43-49). The ascorbic acid used in the formulation can be conventional dry powder (anhydrous). Ascorbic acid is an antioxidant. However, Demopoulos does not teach a composition comprising mixed slats of glucosamine.

Scheck et al teach mixed salts of glucosamine sulfate and metal halides like potassium chloride are well known and that such mixed salts are used in compositions instead of glucosamine sulfate since glucosamine sulfate is unstable in view of its highly hygroscopic nature (col. 1, lines 18-28).

Rovati teaches a stable combined salt comprising glucosamine sulfate and glucosamine hydrochloride in the presence of a stabilizer (col. 5, lines 30-46).

The Merck Manual (entry # 2387) teaches that citric acid is a solid tricarboxylic hydroxy acid.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the prior art above to make a solid formulation comprising

glucosamine sulfate or a mixed salt of glucosamine sulfate hydrochloride or glucosamine sulfate potassium chloride, an aliphatic hydroxylated carboxylic acid like citric acid and an antioxidant as instantly claimed, with a reasonable amount of success since the active agents for the composition is seen to be disclosed in the prior art. Adjusting the ratios of the active agents based on the teachings of the prior art and using crystalline citric acid for making a solid formulation based on the teaching of the Merck manual (citric acid is a crystalline solid) is well within the purview of one of ordinary skill in the art.

One of ordinary skill in the art would be motivated to do so since a composition comprising glucosamine sulfate or the mixed salts with a fruit acid and an antioxidant makes the glucosamine sulfate highly stable and less hygroscopic. Hence this combination would produce a composition that is highly stable in a solid dosage form, thereby overcoming the practical difficulty of using glucosamine sulfate like packaging and degradability (Demopoulos, col. 1, lines 25-43).

Conclusion

1. Claims 15-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600